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Notices

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

X-RAY BAGGAGE INSPECTION SYSTEMS

Notice to State Radiation Control Agencies of Radiation Safety Recommendations

The Bureau of Radiological Health, Food and Drug Administration, Department of Health, Education, and Welfare, under the authority conferred by the Public Health Service Act (42 U.S.C. 241 and 243), advises and promotes cooperation among states on matters relating to

the protection of the public health against radiation hazards. The Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b et seq.), an amendment to the Public Health Service Act, further provides for the establishment of an electronic product radiation control program designed to protect the public health and safety.

The Food and Drug Administration on April 27, 1973, issued, to State radiation control agencies, recommendations (guidelines) on radiation safety aspects in the design and use of x-ray systems for routine inspection of hand carried (carry-on) luggage in airline terminals.

These recommendations are conceptual in nature and minor variations providing equivalent radiation protection may be appropriate to meet the needs of individual radiation control programs.

The recommendations were developed following consultation with the Federal Aviation Administration (Department of Transportation), the National Bureau of Standards (Department of Commerce), the Occupational Safety and Health Administration (Department of Labor), the Executive Committee of the Conference of Radiation Control Program Directors, and manufacturers. The Federal Aviation Administration (FAA), in addition to specifying certain image quality features for x-ray luggage inspection systems and certain requirements on their use, has stated in a directive to its Regional Directors, that "the airline should obtain or require that the manufacturer obtain the permission or license from the State in which the device will be used."

There are presently no Federal standards or regulations specifically directed to the overall radiation safety aspects of these systems. Federal and State agencies have become increasingly concerned with the need for effective and uniform controls on x-ray baggage inspection systems which will assure adequate radiation protection for operators as well as the general public. The manufacture of several of these x-ray systems will be subject to a radiation safety performance standard which is under development and will be published in the FEDERAL REGISTER as a notice of proposed rule making.

During development of the guidelines, representatives of the Bureau of Radiological Health visited six manufacturers of x-ray baggage systems to obtain background information on these systems planned for commercial distribution. Guidelines proposed for the State radiation control agencies were discussed with the manufacturers during these visits. The manufacturers agreed that the proposed guidelines are practical, do not unnecessarily restrict functional objectives of the equipment, and would be desirable to provide uniform evaluation and control among the states.

Concurrently, a survey of all State radiation control agencies was conducted by the Food and Drug Administration to assess the extent of involvement of the states in evaluation of these devices. Over one-half of the State programs re-

ported that they had been contacted by airlines, manufacturers, and industrial agents regarding the need for registration of x-ray baggage systems and radiation safety requirements. Eight states indicated that they had issued special requirements for such systems. Several indicated that their industrial radiography requirements would be applied to the x-ray baggage inspection systems. The states indicated that guidance from the Bureau of Radiological Health would be useful in conducting evaluations and granting approval for use of these x-ray devices.

Because of rapid developments in the design of x-ray systems for the inspection of baggage at airline terminals, proliferation in applications, and requests for guidance from State radiation control programs, it is the opinion of the Food and Drug Administration that radiation safety considerations for this equipment should be outlined in a manner useful for establishing uniform and effective controls.

The Commissioner concludes that the recommendations issued to the State radiation control agencies on April 27, 1973, as set forth below, should help to provide radiation protection for operators, passengers, and others involved in the use of x-ray baggage inspection systems. Therefore, the Commissioner urges that these guidelines be used as a basis for a uniform policy by states granting approval for such equipment.

RECOMMENDATIONS TO STATE RADIATION CONTROL AGENCIES

These recommendations are applicable to x-ray systems used in airline terminals for routine inspection of carry-on baggage.

1. It shall not be possible to insert any part of the body into the primary beam.
2. Radiation exposure shall not exceed 0.5 mR in any one hour at a distance of five centimeters from any point on the external surface of the system when operated under "worst case" conditions.
3. The control panel shall be equipped with a key lock. It shall not be possible to remove the key in the "on" position.
4. Doors and access panels which prevent entry to an area where the exposure may exceed 0.5 mR in one hour shall be interlocked.
5. Means shall be provided to indicate to the operator when x-rays are being produced.
6. A deadman switch shall be provided on the exposure controls. The location of the switch will be such that the operator has a clear view of the x-ray system.

RATIONALE AND EXPLANATION OF RECOMMENDATIONS

RECOMMENDATION 1.

The most significant hazard associated with these systems is human exposure to the primary beam of radiation. Generally, operators are not well trained in the hazards of radiation and may not apply diligent caution to prevent exposure of personnel. To minimize exposure, this recommendation is intended to necessitate engineered safeguards to

prevent, during routine operations, direct beam exposure of any part of the body, including extremities.

RECOMMENDATION 2.

In the absence of conclusive data regarding the effects of low level irradiation, the underlying philosophy of radiation protection is to maintain radiation exposure of personnel as low as practicable. The guideline of 0.5 mR in any one hour at 5 centimeters from the external surface of the device has been developed for other electronic products used in areas accessible to the public. Due to the nature of operation, it is anticipated that the actual exposure to any individual will be considerably less than that generally considered acceptable by national and international standards-setting organizations.

It is intended that test measurements be made under conditions which maximize radiation levels at accessible areas. In those situations where ports are provided to transport objects into or out of the system, the external surface should be considered as the imaginary plane across the opening.

RECOMMENDATION 3.

Since this equipment is used in public areas and could be hazardous when operated without supervision, it is essential that provisions be provided to secure the system to prevent unauthorized use. It is intended that the key lock feature will provide this security.

Likewise, it is important that the system is capable of being turned off at any time. It is thus recommended that the key be captured in the "on" position to prevent someone inadvertently carrying off, or otherwise losing, the key when the system is energized.

RECOMMENDATION 4.

Doors and access panels are frequently provided as a means of preventing access to areas where excessive radiation levels may be present. Recommendations for interlocking is provided to insure that x-radiation production is automatically terminated when access to the source of radiation is possible. This prevents risk of unnecessary radiation exposure when protective features are removed or opened.

RECOMMENDATION 5.

An "X-RAY ON" indicator is recommended to clearly indicate the status of x-ray production and potential for exposure.

RECOMMENDATION 6.

The deadman switch feature is recommended to insure operator control of the system at all times when x-rays are being produced. It is also recommended that the device be located in a position such that the operator can maintain surveillance of the system and have the means available to immediately terminate x-radiation production in emergency situations.

Those interested persons who wish to submit comments or suggestion in con-

nection with the recommendations listed above should send them to Hearing Clerk, Food and Drug Administration, Room 6-86, 5600 Fishers Lane, Rockville, MD 20852, on or before September 7, 1973. The comments will be considered during further development of the recommendations for use by states in evaluation of x-ray baggage inspection systems.

Dated: August 1, 1973.

SAM D. FINE,
*Associate Commissioner
for Compliance.*

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